Remarks/Arguments

Claims 1, 3 to 6, 14 to 16 and 27 to 28 are presently pending. Claims 1 and 6 are amended, without prejudice, as requested by the Examiner. Claims 2, 7 to 13 and 17 to 26 are canceled, without prejudice. Claims 3 to 5 and 14 to 16 are withdrawn. New claims 27 to 28 have been added. Support for the new claims can be found at least in the specification at pages 5 to 7. No new matter has been added.

Applicants reserve the right to pursue subject matter that remains after the prosecution of the present application in a future continuing patent application, for example, a division.

Rejection Under 35 U.S.C. § 102(a)

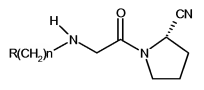
Claims 9 and 18 are rejected under 35 U.S.C. § 102(a) as allegedly anticipated by U.S. Patent No. 6,166,063 to Villhauer ("Villhauer"). Although applicants do not agree, it is respectfully submitted that this rejection is moot in view of the cancelation of claims 9 and 18.

Rejections Under 35 U.S.C. § 103(a)

Claims 1, 6 to 7 and 11 are newly rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Villhauer in view of U.S. Patent No. 6,262,188 to Luskey et al. ("Luskey"). Applicants respectfully traverse this rejection as the combination of Villhauer and Luskey (*arguendo*) does not produce the presently claimed invention.

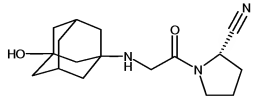
"A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field" (*In re Kotzab*, 55 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000)). "The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time" (*In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) (quoting *Interconnect Planning Corp. v. Feil*, 227 U.S.P.Q. 543, 547 (Fed. Cir. 1985)). To establish a *prima facie* case of obviousness, the examiner must show reasons that the skilled artisan, with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed (*see In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998)).

Applicants' claims define methods of treating hyperlipidemia comprising administration of a therapeutically effective amount of a compound of formula I



(I)

wherein R is substituted adamantyl; and n is 0 to 3 (*see*, e.g. claim 1). Applicants' claims further define method of treating hyperlipidemia comprising administration of a therapeutically effective amount of a compound of formula IC

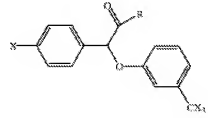


(IC)

(*see*, e.g. claim 6).

Villhauer discloses compounds of said formula IC for methods of treating conditions mediated by dipeptidyl peptidase-IV ("DPP-IV") inhibitors. As acknowledged by the Action at page 7, paragraph 1, Villhauer does not disclose methods of treating hyperlipidemia. Villhauer also does not provide any suggestion or motivation to use the compounds of formula IC to treat conditions other than those mediated by DPP-IV inhibitors. To cure the deficiencies in Villhauer, the Action cites Luskey.

Luskey discloses halofenate compounds of formula I



for use in treating insulin resistance, Type 2 diabetes and hyperlipidemia (*see* Luskey at Col. 3, lines 49 to 66 and Col. 4 lines 1 to 24). In particular, as the halofenate of Luskey treats both diabetes and hyperlipidemia, and as hyperlipidemia is allegedly a subpopulation within the general population of diabetics, the Action cites Luskey for the proposition that one of ordinary skill in the art would be suggested to use all compounds that treat diabetes for the treatment of hyperlipidemia (*see* Action at page 7, paragraph 2). This proposition is, however, incorrect.

Halofenate is in a completely different class of compounds than the DPP-IV inhibitors of Villauer, namely being a peroxisome proliferator-activated receptor ("PPAR") agonist. One of ordinary skill in the art would thus not be suggested to use a DPP-IV inhibitor to treat hyperlipidemia in addition to diabetes merely because another class of compounds with a different mode of action, such as the PPAR agonist of Luskey, is suggested for treatment of both hyperlipidemia and diabetes. One of ordinary skill in the art would further not be suggested to use all diabetes drugs to treat hyperlipidemia, as it is known that not all diabetes drugs, including other PPAR agonists and DPP-IV inhibitors, have a hyperlipidemic effect. In fact, certain other diabetes drugs actually cause increased levels of lipids or have no effect on a patient's lipid

profile. For example, 8 mg doses of Avandia, a PPAR agonist, caused an increase in LDL by 18.6% (*see, e.g.*, Table 7 on page 23 of the Avandia FDA label of October 20, 2008 (attached)). Doses of Januvia, a DPP-IV inhibitor, did not have a significant effect on the patient's lipid profile, being "similar to placebo" (*see, e.g.* page 12, paragraph 6 of the Januvia FDA label of September 24, 2010 (attached)). As such, Luskey is incapable of providing one skilled in the relevant pharmaceutical art a suggestion or motivation to modify Villhauer by using the DPP-IV inhibitory compounds of Villhauer for the treatment of hyperlipidemia instead of diabetes. The Action thus fails to provide requisite motivation to combine and modify Villhauer and Luskey in such a way as to produce the presently claimed invention, absent the use of impermissible hindsight.

Indeed, the Patent Office has the burden of presenting factual evidence that would indicate that the claimed methods are prima facie obvious (*In re Lunsford*, 148 U.S.P.Q. 721 (C.C.P.A. 1966)). In the absence of such a showing, such a rejection is based upon impermissible hindsight (*In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992) ("it is impermissible for an Examiner, in proffering a 35 U.S.C. § 103 rejection, to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art to render the claimed invention obvious.")). Accordingly, reconsideration and withdrawal of the rejection are requested respectfully for at least this reason.

Double Patenting

Applicants request that the provisional obviousness-type double patenting rejections be deferred pending some identification of allowable subject matter, at which time applicants will consider the filing of a suitable terminal disclaimer.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Action of record. If there are any issues that can be resolved by a telephone conference, the Examiner is invited to call the undersigned attorney.

It is hereby requested that the term to respond to the Action of July 14, 2010 be extended pursuant to 37 C.F.R. § 1.136(a) for three (3) months, from October 14, 2010 to January 14, 2010. The Commissioner is hereby authorized to charge any fees required to Deposit Account No. **19-0134** in the name of Novartis.

Respectfully submitted,

/Cozette M. McAvoy/
Cozette M. McAvoy
Attorney for Applicants
Reg. No. 60,457

Novartis
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-9273
Date: January 14, 2010